REMARKS

Review and reconsideration of the Office Action of February 28, 2003, is respectfully requested in view of the above amendments and the following remarks.

Applicants are pleased to see that the Examiner withdrew all his previous rejections.

The newly cited references, Rosen et al. and Edwards et al., describe a device and method for the treatment of the prostate. A flexible catheter is introduced through the urethra to the prostate. Then, electrical energy is introduced to the prostate tissue in order to cause ablation of tissue. The electrical energy is introduced by two electrodes.

In figures 1-10 of the Rosen reference, the two electrodes are the tip of two stylets. In figures 11-15 of the same reference, the two electrodes are the central needle and the coaxial layer of the stylet.

Since the catheter and the stylet guided in the catheter are introduced through the urethra, the catheter and the stylet have to be flexible and should not be able to penetrate the tissue.

The present invention is directed to cannula used for introducing a **flexible catheter** into the nerve sheath. Therefore, the cannula must be **rigid and must have a sharp tip**, so that the tissue and, especially, the robust nerve sheath can be pierced by the cannula. Further, the cannula is unipolar, i.e. the cannula has only one electrode. A **unipolar cannula** (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

In contrary, the ablation of tissue according to the Rosen and Edwards references needs sufficient electrical power, which can only be produced by a bipolar device.

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Paragraphs 1 - 15 (Obviousness)

The Examiner rejects Claims 12-21 and 23-25 under 35 U.S.C. 103(a) as being obvious over Rosen et al., 5,720,718, in view of Edwards et al., 5,536,240.

The position of the Examiner can be found on pages 2-4 of the Office Action.

Applicants respectfully traverse.

Regarding the Rosen reference

Applicants note that compared with independent Claims 12, 19, 23, and 26, the Rosen reference fails to teach: 1) a **rigid** hollow tube made of steel; 2) a cannula in which a catheter can be inserted; 3) the sharp tip is not covered by the sleeve; and 4) an unipolar cannula.

Regarding point 1

The Rosen reference describes a device and method for the treatment of the prostate. A flexible catheter is introduced through the urethra to the prostate. Then, electrical energy is introduced to the prostate tissue in order to cause **ablation of tissue.** The electrical energy is introduced by two electrodes.

The probe comprises **a catheter** having a **flexible** tube having a sharp end (see Claim 1 and columns 5-6), a body part, a connector and a dielectric cover.

The Rosen reference discloses a **flexible** tube (column 6, lines 34-39). Because of the flexibility of the tube, it must be inserted with the aid of a wire guide.

The cannula, according to the present invention, is a

cannula tube that is used **to pierce** a tissue. Therefore, it is necessary that the cannula **is rigid and has a sharp piercing tip.**

After the tissue and the nerve area are penetrated by the rigid cannula with the sharp tip, the position of the tip is verified by electro stimulation. If the position of the tip of the cannula is correct, the flexible catheter is introduced through the cannula into the nerve sheath or the spinal channel where the flexible catheter can be advanced without any resistance.

The cited reference teaches a catheter.

Also, nowhere in the Rosen reference can be found the teaching that the tube is made of steel. The present invention requires an electrically conductive tube made of steel (rigid), thus the tube does not bend when it is inserted into the skin.

Having the tube rigid (steel) avoids having to use a wire guide, which makes the mechanical design of the present invention simpler than the Rosen invention.

Since the catheter and the stylet guided in the catheter are introduced through the urethra, the catheter and the stylet have to be flexible and should not be able to penetrate the tissue.

The present invention is directed to cannula used for introducing a flexible catheter into the nerve sheath. Therefore, the cannula must be rigid and must have a sharp tip, so that the tissue and, especially, the robust nerve sheath can be pierced by the cannula. Further, the cannula is unipolar, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical

power.

In contrary, the ablation of tissue according to the Rosen and Edwards references needs sufficient electrical power, which can only be produced by a bipolar device.

Regarding point 2

The reference teaches a catheter. The present invention concerns a cannula to be introduced into a nerve sheath, through which a flexible catheter can be inserted.

The present invention, in contrast, is concerned with the task of providing a unipolar cannula for continuous anesthesia, which, through simple construction and simple operation, unites:

(a) the ability to place a catheter (the catheter itself not being a part of the present claims),

(b) the ability to administer anesthetic,

(c) no need for separate electrical conductors to supply electricity for electro-stimulation to the tip of the catheter, since the body of the catheter is used as a conductor, and

(d) the advantage of very precise electro-stimulation.

Where it was previously necessary to, e.g., simultaneously introduce a hose for anesthetic and a separate unipolar canula into a plastic cannula tube, the inventive unipolar **cannula** can be placed or located with the help of electrical nerve

stimulation. The outer insulating covering of the cannula tube, which leaves only a very small, almost pinpoint area of the tip free (see original claim 7, now claim 18 and also new claim 23 - exposed length about 1mm), makes possible an extraordinarily precise placement of the tip. The unipolar **cannula** can itself be used for the guided introduction of the **catheter**. The connection for electro-stimulation is introduced through the side of the body part and contacts the outside of the electrically conductive cannula tube. This manner of connection does not impede or constrict therewith the axial inlet opening of the body part. After the placement of the unipolar cannula with the help of electro-stimulation, the catheter can be introduced through the cannula tube, without any requirement that the position of the unipolar cannula must be changed or other measures be taken.

How, if the inventor recognizes that a cannula and a catheter are two different devices that can be used together, can the Examiner indicate that a catheter is the same as a cannula?

Regarding point 3

Nowhere in the Rosen reference can be found the teaching that the tip is exposed (not covered by the insulation cover).

Further, Applicants note that almost all the embodiments of the medical probe according to Rosen require a non-conductive cover, except the embodiment that includes a sharp tip. (see columns 9-10). The present invention requires a non-conductive cover.

Applicants also note that the tube of the reference is a stylet, thus the tube is not dimensioned to allow the pass of a catheter.

According to the Webster Dictionary, "stylet" is a stiff **wire, inserted in catheters or other tubular instruments to maintain their shape and prevent clogging.**

Regarding point 4

The cannula of the present invention is unipolar, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

In contrary, the ablation of tissue according to the Rosen reference need sufficient electrical power, which can only be produced by a bipolar device.

Regarding the Edwards reference

Applicants reviewed the reference and note that the reference is directed to a medical probe for treating prostatic hypertrophy of the prostate. The device has a radio frequency electrode including an electrically conductive tube (58) and having a sharpened tip. A **flexible** stylet (54) comprising a needle (56) is axially moveable in the tube (58). The tube is enclosed within a non-conductive layer. The tube is constructed of conductive metal such as steel. The tube is introduced into

the walls of the urethra to a pre-selected length to target the tissue.

Applicants also note that the tube of Edwards does not have a sharp tip. The **flexible** needle that is introduced in the tube is the one having the sharp tip, thus it must be inserted with the aid of a guide.

The cannula of the present invention exhibits a **sharp** tip, so that it can pierce tissue. **The tip, which serves as an electrode,** is not a separate part attached to the cannula tube, but is rather formed by the tip of the cannula tube itself.

In addition, Applicants note that the reference is not directed to a cannula for anesthesia. Thus, Applicants do not consider this reference to be in the same field of the invention.

The cannula of the present invention is unipolar, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

In contrary, the ablation of tissue, according to the Edwards reference, need sufficient electrical power, which can only be produced by a bipolar device.

Combining the references

The Rosen et al and Edwards et al. references describe a device and method for the treatment of the prostate. A flexible catheter is introduced through the urethra to the prostate. Then, electrical energy is introduced to the prostate tissue in order to cause ablation of tissue. The electrical energy is introduced by two electrodes.

In figures 1-10 of the Rosen reference, the two electrodes are the tip of two stylets. In figures 11-15 of the same reference, the two electrodes are the central needle and the coaxial layer of the stylet.

Since the catheter and the stylet guided in the catheter are introduced through the urethra, the catheter and the stylet have to be flexible and should not be able to penetrate the tissue.

The present invention is directed to cannula used for introducing a flexible catheter into the nerve sheath. Therefore, the cannula must be rigid and must have a sharp tip, so that the tissue and, especially, the robust nerve sheath can be pierced by the cannula. Further, the cannula is unipolar, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

In contrary, the ablation of tissue, according to the Rosen and Edwards references, needs sufficient electrical power, which can only be produced by a bipolar device.

Thus, none of the references taken alone or combined teaches the present invention.

Paragraphs 16 - 18 (Obviousness)

The Examiner rejects Claim 22 under 35 U.S.C. 103(a) as being obvious over Rosen et al., 5,720,718, in view of Edwards et al., 5,536,240, and further in view of Schaer, 5,782,760. Rosen et al. in view of Edwards et al. discloses the invention substantially as claimed, see above, except for a ramp is formed on the inside of the distal end of the cannula tube.

The position of the Examiner can be found on page 4 of the Office Action.

Applicants respectfully traverse for the same reasons set forth in the above paragraphs and the following remarks:

Applicants note that the tip of the cited reference is not sharp, but rather dull, so that the vein through which it is advanced is not damaged. The tip of the reference is not designed for, or capable of, use for ***piercing*** of tissue.

Applicants also note that in column 3, lines 28-33, the reference indicated that the shaft is overlapped with a jacket to prevent exposure of sharp **metallic edges that can cause damage when the device is advanced through blood vessels**. Thus, the reference is avoiding the use of sharp edges. Thus, the reference is teaching away from the Rosen and Edward references (sharp tip).

A §103 rejection based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, is not proper, and the *prima facie*

case of obviousness cannot be properly made. In short, there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. In re Gordon 221 USPQ 1125 (Fed. Cir 1984).

Further, Applicant would like to point out to the Examiner that Claim 22 is novel in view of its dependency with novel Claim 12.

Favorable consideration and early issuance of the Notice of Allowance is respectfully requested. The Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,

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AMENDMENT C

Attorney Docket: 2368.098

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT C for U.S. Application No. 09/438,759 filed November 11, 1999, was deposited in first class U.S. mail, postage prepaid, addressed: Attn: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on **May 20, 2003**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

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